



Declaration of Conformity
European Directive 98/79/EC

Dok.Nr.:TF0003.03

Ersetzt: TF0003.02

Attachment 3 of DO0081 i.t.c.v.

Manufacturer: Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Brunner Str. 67
1230 Vienna
AUSTRIA

Product:

valid from **LOT** :

REF 5005046 TECHNOCLOT® PT Owren automated 10x10 ml
REF 5005044 TECHNOCLOT® PT Owren automated 10x4 mL

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6A52BA0

Classification: IVD, "all other classes"
European directive: 98/79/EC

We declare that the above mentioned products meets all applicable requirements set out in Annex III (excluding section 6) of the Directive 98/79/EC and take sole responsibility of the these products. These products have been manufactured and classified as "all other classes" according to the European Directive 98/79/EC.



Date: 20-May-2022
Valid until: 25-May-2026

V. Binder
Company director

S. Schwingenschlög
QM-Manager

Amendment to Declaration of Conformity

European Directive 98/79/EC



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Temp.: TFC0361.03

Pursuant to Article 110 (3b) of EU 2017/746 (IVDR) concerning in vitro diagnostic medical devices, amended through Regulation (EU) 2024/1860, the validity of the Declaration of Conformity is adapted to comply with the transitional provisions.

Manufacturer: Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Brunnerstrasse 67
1230 Vienna, Austria

This amendment confirms and extends the validity of the respective Declaration of Conformity (IVDD) for Class B devices until 31.12.2029 (Art. 110 (3b) (c)) and Class C devices until 31.12.2028 (Art. 110 (3b) (b)). It is only valid in combination with the following EC Declaration of Conformity (IVDD):

Class B Devices:

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| 5344512 | APC Control Kit 2x1 ml |
| 5344510 | APC Resistance Kit - TC 120 T. |
| 5344515 | APC Resistance Kit - TC 40 T. |
| 5114008 | F II Mangelplasma immunodepleted 5x1 ml |
| 5134004 | F V Mangelplasma, immunads 5x1 ml |
| 5144015 | F VII Mangelplasma, immunads 5x1 ml |
| 5174006 | F X Mangelplasma, immunodepl. 5x1 ml |
| 5174004 | F X Mangelplasma, nativ 5x1 ml |
| 5184006 | F XI Mangelplasma, immunads., 5x1 mL |
| 5184004 | F XI Mangelplasma, nativ 5x1 ml |
| 5194007 | F XII Mangelplasma, immunads., 5x1 mL |
| 5194008 | F XII Mangelplasma, nativ 5x1 ml |
| 5204006 | Fitzgerald Trait Plasma 2x1 ml |
| 5343005 | Lupus Anticoagulant Test 6 T. |
| 5343010 | Lupus Inhibitorplasma 2x1 ml |
| 5343019 | Lupus Inhibitorplasma 5x1 ml |
| 5343022 | Platelet Poor Plasma 5x2 ml |
| 5343021 | Lupus Inhibitorplasma Low 5x1 ml |
| 5205006 | Fletcher Trait Plasma 2x1 ml |
| 5346806 | Protein C Mangelplasma 2x1 ml |
| 5341031 | Protein S deficient plasma immunodepleted |
| 5345003 | Technochrom C1-Inhibitor 30 T. |
| 5345004 | Technochrom C1 INH 2G |
| 5360010 | Technochrom FXIII 3x3 ml |
| 5342631 | Technochrom Plasmin INH |
| 5340251 | Technochrom Plasminogen |
| 5341013 | Technochrom Protein C 30 T. |
| 5341014 | Technochrom Protein C 2G |
| 5343052 | Technoclot® DRVVT Confirm |
| 5343050 | Technoclot® DRVVT Screen |
| 5343056 | Technoclot Ecarin |

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| 5343016 | Technoclot LA Confirm 5x1 ml |
| 5343012 | Technoclot LA Screen 5x2 ml |
| 5343058 | Technoclot Lupus aPTT |
| 5343060 | Technoclot Lupus aPTT |
| 5346200 | Technoclot Protein C |
| 5341030 | Technoclot Protein S |
| 5343054 | Technoclot Taipan |
| 4848200 | Technoleia Free Protein S |
| 4848300 | Technoleia VWF:Ag |
| 4848310 | Technoleia VWF:Ag CAL Set |
| 5700100 | TECHNOSCREEN ADAMTS-13 Activity |
| 5450601 | Technozym ADAMTS-13 Antigen, 96 T. |
| 5450661 | Technozym ADAMTS-13 Calibrator Set, 5 x 0.5 mL |
| 5450663 | Technozym ADAMTS-13 Control Set, 2 x 0.5 mL |
| 5450401 | Technozym ADAMTS-13 INH, 96 T. |
| 5450451 | Technozym ADAMTS-13 INH, 48 T. |
| 5450461 | Technozym ADAMTS-13 INH Calibrator Set, 5 x 0,5 ml |
| 5450463 | Technozym ADAMTS-13 INH Control Set 2 x 0,5 ml |
| TC16075 | Technozym PAI-1 Actibind ELISA Kit 96 T. (new) |
| TC16077 | Technozym PAI-1 Actibind Calibrator Set, 5 x 0.5 mL |
| TC16079 | Technozym PAI-1 Actibind Control Set, 2 x 0.5 mL |
| TC12075 | Technozym PAI-1 ELISA Kit 96 T. (new) |
| TC12077 | Technozym PAI-1 Antigen Calibrator Set, 5 x 0.5 mL |
| TC12079 | Technozym PAI-1 Antigen Control Set, 2 x 0.5 mL |
| TC12021 | Technozym Protein C ELISA 96 T. |
| TC12007 | Technozym t-PA Ag EDTA ELISA |
| TC12001 | Technozym t-PA Antigen Calibrator Set, 5 x 0,5 mL |
| TC12003 | Technozym t-PA Antigen Control Set, 2 x 0,5 mL |
| 5450201 | Technozym vWF:Ag ELISA 96 T. |
| 5450210 | Technozym vWF:Ag Calibrator Set, 5 x 0,5 mL |
| 5450212 | Technozym vWF:Ag Control Set, 2 x 0,5 mL |

Class C Devices:

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| 5010004 | Ak-Calibrant 4x1 ml |
| 5010024 | AK-Verification Kit, 3 x 1 ml |
| 5006347 | Ceveron TGA CAL Set, 1 Set |
| 5006011 | Ceveron TGA RB Kit, 120 T. |
| 5006015 | Ceveron TGA RC High Kit, 120 T. |
| 5006013 | Ceveron TGA RC Low Kit, 120 T. |
| 5021055 | Coagulation Control A 5x1 ml |
| 5021060 | Coagulation Control A 50x1 ml |
| 5011050 | Coagulation Control AK 5x1 ml |
| 5011060 | Coagulation Control AK 50x1 ml |
| 5020040 | Coagulation Control N 5x1 ml |

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| 5020050 | Coagulation Control N 50x1 ml |
| 5220110 | Coagulation Reference 5x1 ml |
| 5220120 | Coagulation Reference 50x1 ml |
| 5035060 | Dapttin TC 5x2 ml |
| 5035090 | Dapttin TC 6x10 ml |
| 5035100 | Dapttin TC 20x10 ml |
| 5164003 | F IX Mangelplasma immundepl. 5x1 ml |
| 5164004 | F IX Mangelplasma immundepl. 50x1 ml |
| 5164008 | F IX Mangelplasma, nativ 5x1 ml |
| 5164016 | F IX Mangelplasma, nativ 50x1 ml |
| 5154002 | F VIII Mangelplasma immunads. 5x1 ml |
| 5154004 | F VIII Mangelplasma immunads. 50x1ml |
| 5154007 | F VIII Mangelplasma, nativ 5x1 ml |
| 5154016 | F VIII Mangelplasma, nativ 50x1 ml |
| 5159010 | F VIII Inhibitorplasma HCV neg. 5x1 ml |
| 5159008 | F VIII Inhibitorplasma 5x1 ml |
| 5152009 | F VIII Inhibitor Reagenziensatz HCV neg. 2-4 T. |
| 5152005 | F VIII Inhibitor Reagenziensatz 2-4 T. |
| 5138080 | Fibrinogen Reagenz (120 T.) 5x5 ml |
| 5138085 | Fibrinogen Reagenz 5x2 ml |
| 5138005 | Fibrinogen Reagent kit 45 T. |
| 5035118 | Siron LIS(aPTT liquid) 2x4 ml |
| 5035119 | Siron LIS (aPTT liquid) 10x4 ml |
| 5035121 | Siron LIS (aPTT liquid) 10x10 ml |
| 5035105 | Siron LS(aPTT liquid) 2x4 ml |
| 5035107 | Siron LS (aPTT liquid) 10x4 ml |
| 5035109 | Siron LS (aPTT liquid) 10x10 ml |
| 5340250 | Technochrom anti Xa Kit 80.T |
| 5340224 | Technochrom AT III Kit 80 T. |
| 5340225 | Technochrom AT III manual method Kit ~ 39 T. |
| 5347000 | Technochrom DTI |
| 5344101 | Technochrom FVIII:C 40 T. |
| 5344102 | Technochrom FVIII 2G |
| 5344104 | Technochrom FVIII 2G CAL Set |
| 5021070 | Technoclot Control A, 10 x 1 ml |
| 5021075 | Technoclot Control A, 50 x 1 ml |
| 5021062 | Technoclot Control A2, 10 x 1 ml |
| 5021064 | Technoclot Control A2, 50 x 1 ml |
| 5020070 | Technoclot Control N, 10 x 1 ml |
| 5020075 | Technoclot Control N, 50 x 1 ml |
| 5100025 | Technoclot DTI Kit, 2 x 20 T. |
| 5005044 | Technoclot PT Owren automated 10x4 mL |
| 5005046 | Technoclot PT Owren automated 10x10 ml |
| 5005100 | Technoclot PT Owren Capillary Calibration Set |

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| 5005102 | Technoclot PT Owren Capillary Control Set |
| 5005032 | Technoclot PT Owren manual 10x4 mL |
| 5005037 | Technoclot PT Owren manual 10x10 ml |
| 5003220 | Technoclot PT PLUS 5x4 ml |
| 5003222 | Technoclot PT PLUS 10x10 ml |
| 5800100 | Technofluor ADAMTS13 Activity 25 T. |
| 5800102 | Technofluor ADAMTS13 Activity 0 CAL 2x1 ml |
| 5800200 | Technofluor FXIII Activity |
| 4847200 | TechnoLEIA D-Dimer Latex Kit 150 T. |
| 4847210 | TechnoLEIA D-Dimer Latex Kit 50 T. |
| 4847236 | TechnoLEIA D-Dimer Calibrator 0 ng/ml 2 x 1 mL |
| 4847234 | TechnoLEIA D-Dimer Calibrator 3000 ng/ml 2 x 1 mL |
| 4847230 | TechnoLEIA D-Dimer Control high 5x1 ml |
| 4847232 | TechnoLEIA D-Dimer Low Control 5 x 1 mL |
| 4848100 | Technoleia FDP |
| 4848110 | Technoleia FDP CAL Set |
| 4848120 | Technoleia FDP CON Set |
| 5003009 | Technoplastin HIS 12x2 ml |
| 5003021 | Technoplastin HIS 20x10 ml |
| 5003026 | Technoplastin HIS 6x10 ml |
| 5003030 | Technoplastin HIS 2x10 ml |
| 5003010 | Technoplastin HIS, 12x4 ml f. Ceveron |
| 5003022 | Technoplastin HIS, 20x20 ml f. Ceveron |
| 5003028 | Technoplastin HIS, 6x20 ml f. Ceveron |
| 5090280 | Technoview allXa CON Set |
| 5090269 | TECHNOVIEW Apixaban CAL 5x1 ml |
| 5090270 | TECHNOVIEW Apixaban CONT H 5x1 ml |
| 5090271 | TECHNOVIEW Apixaban CONT L 5x1 ml |
| 5090140 | TECHNOVIEW Argatroban CAL Set 5x1 ml |
| 5090144 | TECHNOVIEW Argatroban CONT H 5x1 ml |
| 5090142 | TECHNOVIEW Argatroban CONT L 5x1 ml |
| 5090010 | TECHNOVIEW Arixtra CAL 5x1 ml |
| 5090014 | TECHNOVIEW Arixtra CONT H 6x1 ml |
| 5090012 | TECHNOVIEW Arixtra CONT L 6x1 ml |
| 5090210 | TECHNOVIEW Dabigatran CAL 5x1 ml |
| 5090212 | TECHNOVIEW Dabigatran CONT H 5x1 ml |
| 5090214 | TECHNOVIEW Dabigatran CONT L 5x1 ml |
| 5090250 | TECHNOVIEW Edoxaban CAL Set 5x1 ml |
| 5090253 | TECHNOVIEW Edoxaban CONT High 5x1 ml |
| 5090251 | TECHNOVIEW Edoxaban CONT Low 5x1 ml |
| 5090252 | TECHNOVIEW Edoxaban CONT Medium 5x1 ml |
| 5090040 | TECHNOVIEW LMW CAL 5x1 ml |
| 5090046 | TECHNOVIEW LMW High Control 5x1 ml |
| 5090042 | TECHNOVIEW LMW Low Control 5x1 ml |

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| 5090044 | TECHNOVIEW LMW Medium Control 5x1 ml |
| 5090110 | TECHNOVIEW Orgaran CAL 5x1 ml |
| 5090114 | TECHNOVIEW Orgaran CONT H 5x1 ml |
| 5090112 | TECHNOVIEW Orgaran CONT L 5x1 ml |
| 5090170 | TECHNOVIEW Rivaroxaban CAL 5x1 ml |
| 5090171 | TECHNOVIEW Rivaroxaban CAL High 5x1 ml |
| 5090174 | TECHNOVIEW Rivaroxaban CONT H 5x1 ml |
| 5090172 | TECHNOVIEW Rivaroxaban CONT L 5x1 ml |
| 5090173 | TECHNOVIEW Rivaroxaban CONT M 5x1 ml |
| 5090070 | TECHNOVIEW UFH CAL 5x1 ml |
| 5090074 | TECHNOVIEW UFH CONT H 5x1 ml |
| 5090072 | TECHNOVIEW UFH CONT L 5x1 ml |
| 5450701 | Technozym ADAMTS-13 Activity ELISA, 96 T. |
| 5450761 | Technozym ADAMTS-13 Activity CAL Set, 5 x 0.5 mL |
| 5450763 | Technozym ADAMTS-13 Activity CONT Set, 2 x 0.5 mL |
| 5450501 | Technozym ADAMTS-13, 2 x 48 T. |
| 5450551 | Technozym ADAMTS-13, 48 T. |
| 5450561 | Technozym ADAMTS-13 Calibrator Set, 5 x 0.5 mL |
| 5450563 | Technozym ADAMTS-13 Control Set, 2 x 0.5 mL |
| 2599006 | Technozym D-Dimer ELISA Kit, 96 T. |
| 5450310 | Technozym vWF:CBA Calibration Set, 5 x 0,5 mL |
| 5450312 | Technozym vWF:CBA Control Set, 2 x 0,5 mL |
| 5450311 | Technozym vWF:CBA Collagen Typ I, 96 T. |
| 5450301 | Technozym vWF:CBA ELISA 96 T. |
| 5100005 | Thrombin Reagent (6x6 ml) 180 T. |

A handwritten signature in blue ink, appearing to read 'Veronika Binder'.

Veronika Binder

Company Director

Vienna, 19.08.2024

A handwritten signature in blue ink, appearing to read 'Lara Schöllbauer'.

Lara Schöllbauer

Head of Regulatory Affairs

Vienna, 19.08.2024